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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,483	09/28/2005	Joerg Rosenberg	M/42135	5340
26474 7590 04/06/2010 NOVAK DRUCE DELUCA + QUIGG LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005				
EXAMINER				
SASAN, ARADHANA				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
04/06/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

***Advisory Action  
Before the Filing of an Appeal Brief***

**Application No.**

10/530,483

**Applicant(s)**

ROSENBERG ET AL.

**Examiner**

ARADHANA SASAN

**Art Unit**

1615

**—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —**

THE REPLY FILED 16 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_ (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Applicant's arguments (filed 03/16/10) have been fully considered but are not found persuasive.

Rejection of claims 1-4, 6-8, 10-19 and 21-22 under 35 U.S.C. 103(a) as being unpatentable over Klimesch et al. (US 5,073,379) in view of Thacharodi et al. (EP 0 960 620 A1)

Applicant argues that it is critical for the purposes of Klimesch et al.'s process that the material exit the extruder in pasty, still plastic and thus moldable form, that in the terms which are used by Klimesch et al., crosslinked PVP per se cannot be deemed "extrudable" as is asserted in the Office action, and that Example 3 of Klimesch et al. does not show or suggest that crosslinked PVP itself is capable of forming a pasty moldable extrudate.

This is not persuasive because Klimesch teaches the extrusion of the mixture comprising crosslinked PVP in Example 3. One of ordinary skill in the art would readily recognize or deem the components of the extrudable mixture, including the crosslinked PVP as "extrudable."

Applicant argues that Klimesch et al. specifically conveys that increasing the amount of auxiliaries at the cost of the amount of binder beyond a weight ratio of at most 1:1 is impracticable. Applicant argues that the non-thermoplastic properties of crosslinked PVP, together with the teaching of Klimesch et al. deter from increasing the amount of the disintegrant at the cost of the amount of binder beyond the at most 1:1 weight ratio as a loss in binding effectivity of the thermoplastic polymer would render the extrudate granular, and the mixture unsuitable for the purposes of the process of Klimesch et al.

This is not persuasive because both Klimesch and Thacharodi teach the incorporation of crosslinked PVP in the process of preparing pharmaceutical compositions. Thacharodi teaches using a high level of crosslinked PVP (66.67 % in Example 6). It is obvious to combine prior art elements according to known methods to yield predictable results and it is also obvious to use a known technique (using a higher level of crosslinked PVP) to improve similar methods (preparing a pharmaceutical composition by

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Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615